

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS:	Conte, <i>et al.</i>	CONF. NO.:	3809
SERIAL NUMBER:	10/507,345	EXAMINER:	Carlos A. Azpuru
FILING DATE:	March 24, 2005	ART UNIT:	1615
FOR :	System for the Controlled Release of Active Ingredients		

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR § 1.132 OF UBALDO CONTE

I, Ubaldo Conte, of Via Treviglio, 6-21052 Busto Arsizio, Italy, declare and state:

1. I have read and understand the subject matter described and claimed in the instant application, United States Patent Application Serial No. 10/507,345 filed March 24, 2005 ("the '345 application"), entitled "A System for the Controlled Release of Active Ingredients."

2. I have read and understand the Office Action mailed on October 29, 2008, understand that claims 1-17 are rejected under 35 U.S.C. §102(b) as being anticipated by US Patent No. 5,650,169 ("Conte").

3. I am a co-inventor of the '345 application.

4. I am also a co-inventor of Conte.

5. I make this Declaration to establish that the therapeutic tablet system for oral administration of one or more active ingredients described in the '345 application is completely coated by a film of polymeric material, insoluble in and impermeable to aqueous fluids, on which one or more incisions of predetermined dimensions and shapes are made. The shape of the



incision is a function of desired rate and progress of release of the active ingredients. The release of active ingredients takes place from an area of the nucleus underlying the surfaces of the film coating delimited by the incision(s); the dimension and shape of the incision(s) imparts functional and structural limitations to this product.

6. I make this Declaration to establish that the process of making the therapeutic tablet system of the current invention described above gives the system a more advantageous release profile for constant steady release of drug than the tablets taught in Conte. The graphs in Exhibit A, submitted herewith, illustrate that the tablets in Conte, on average, initially release over 30-50% of the active ingredient within 15-20 minutes, and after the initial release the release profile tends to flatten out until later when a subsequent release occurs, i.e., the release of active ingredients occurs in pulses. In contrast, the claimed tablet has a substantially linear drug release rate, not "in sequential pulses," where less than 10% drug is released in the first 15-20 minutes, and approximately 50% drug is released in 3-4 hours and the release continued for approximately 7-8 hours. This linear controlled rate is achieved due to the incision on one face of the tablet. The conclusion that the incision(s) is the critical factor in establishing the observed release profile is supported by the data that while the active ingredient is released at different rates as a function of the area of the hole made in the coating, the release profile remains the same. At equal compositions, from the filmed tablet with the circular hole of 7.0 mm in the coating (equal to 38.5 mm<sup>2</sup>) the active ingredient is released at a greater rate with respect to the system with the circular hole of 5.0 mm. (equal to 19.5 mm<sup>2</sup>). The incision(s) on the tablet of the current invention described above is an impermeable coating that fully covers the active ingredients, thus clearly alters the release profile with a pre-determinable and programmable release rate compared to the release profiles of Conte.

7. I also declare and state that the process of making the therapeutic tablet system of the current invention described above gives the tablets greater stability than the tablets taught in Conte. The incision(s) delimited film coating of the tablet of the current invention described above remains intact before contact with aqueous fluids. Thus, the incisions of the therapeutic tablet system of the current invention increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration. Whereas

the tablet in Conte does not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient exposed. I submit that the tablet of the claimed invention is different compared to the tablet in Conte, as Conte does not provide a method to stabilize the active ingredient exposed by the abrading process.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that willful false statements may jeopardize the validity of this application and any patent issuing therefrom.



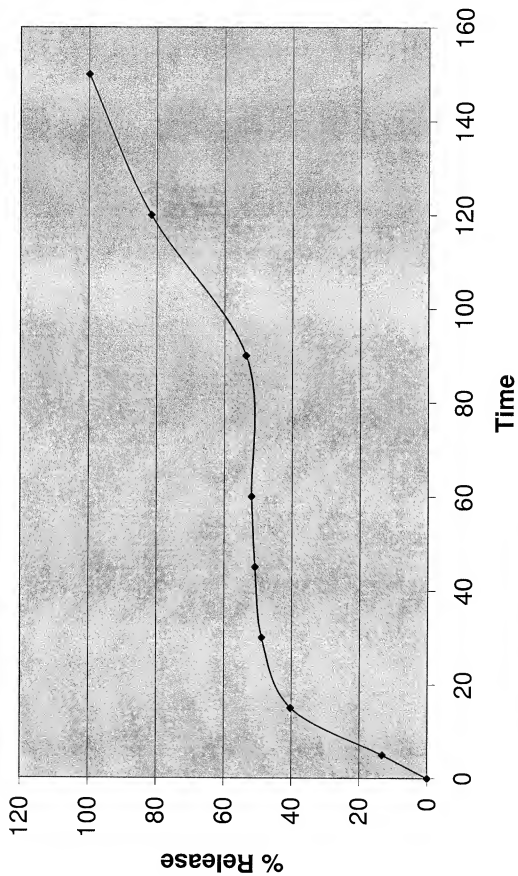
\_\_\_\_\_  
Ubaldo Conte

January 28, 2009

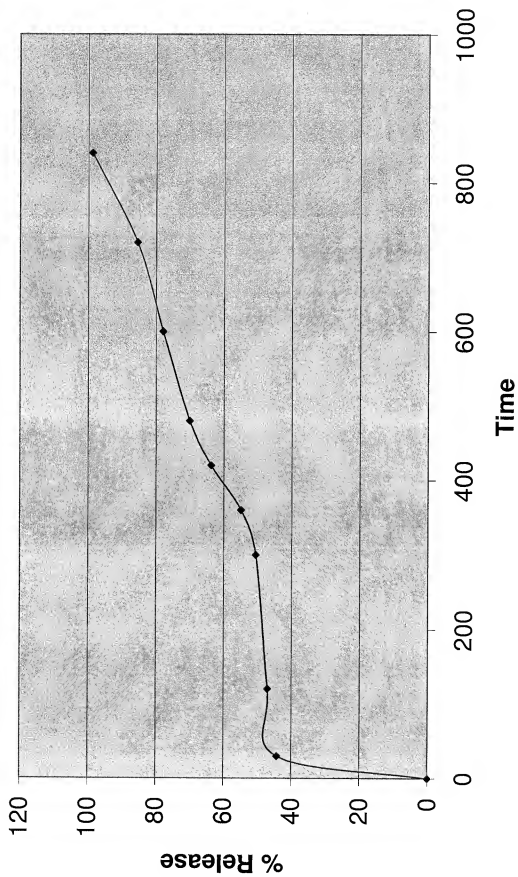
Date

# EXHIBIT A

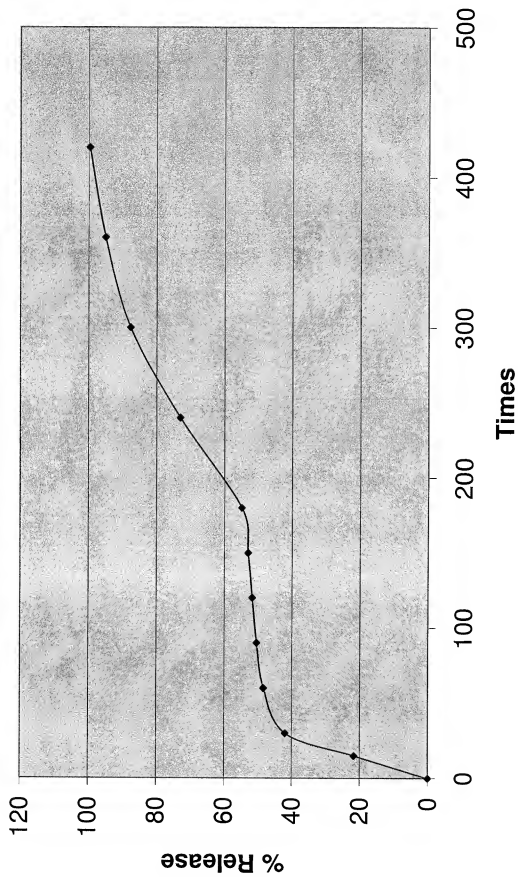
# EG 1 CONTE



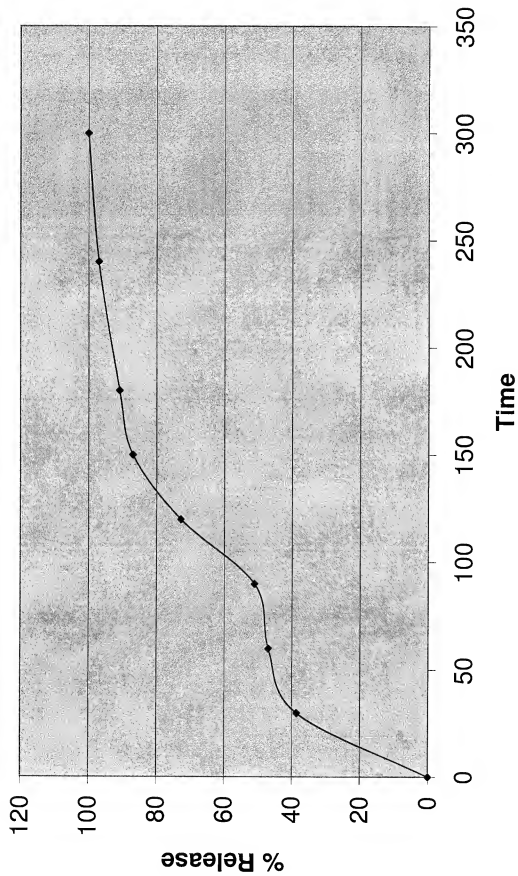
# EG 2 CONTE



# EG3 CONTE

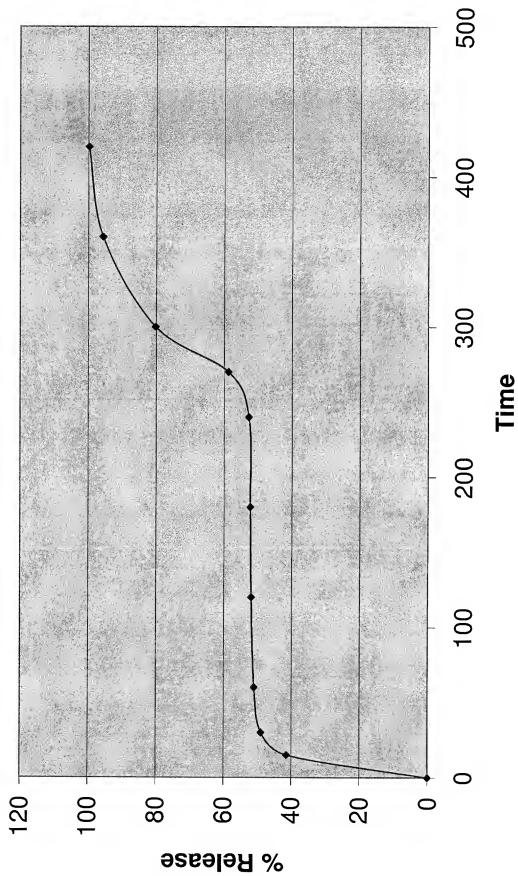


# EG4 CONTE

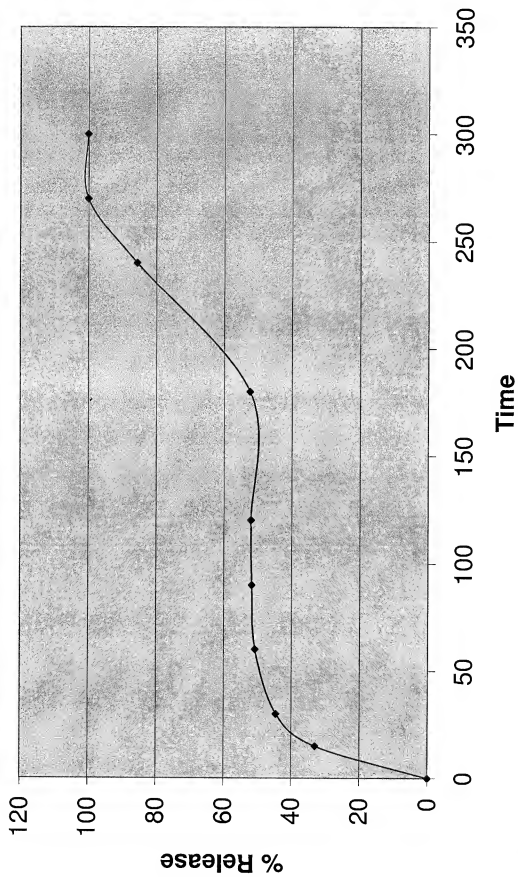




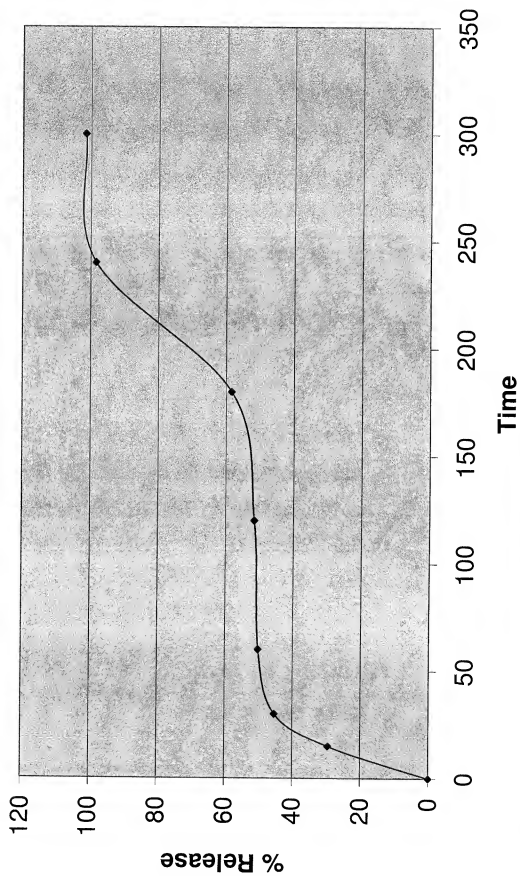
# EG5 CONTE



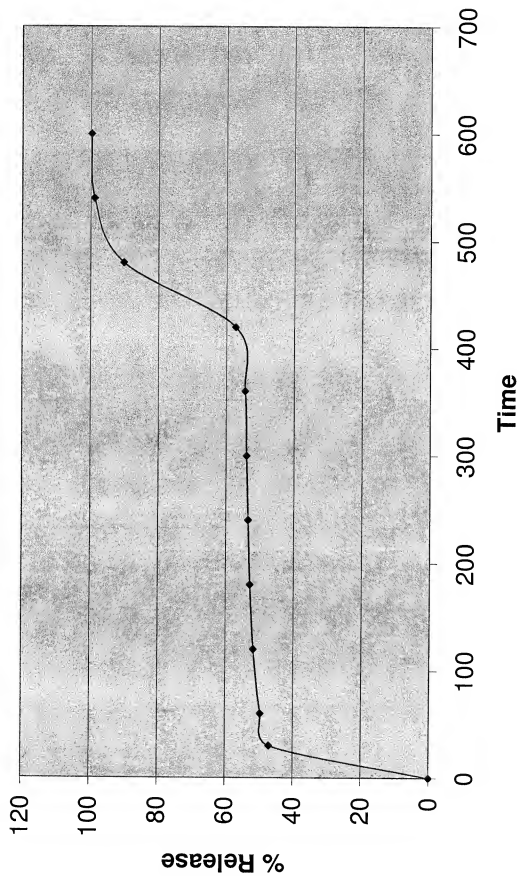
# EG6 CONTE



# EG7 CONTE



# EG8 CONTE



# EXHIBIT B

Table I: Non coated tablet

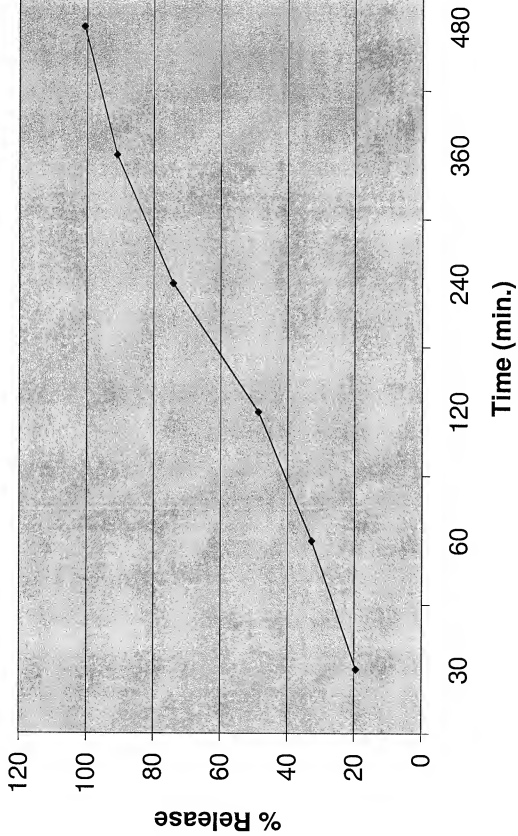


Table I: Hole 19.5 mm2

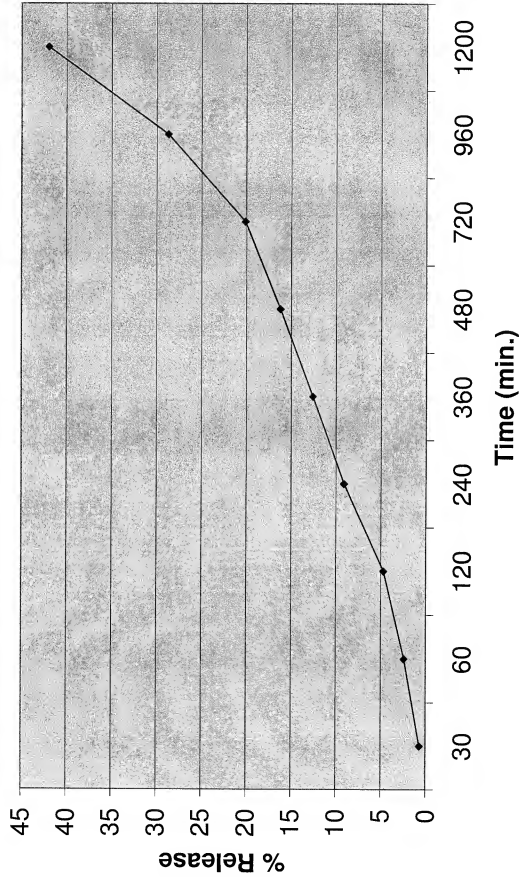


Table I: Hole 38.5 mm2

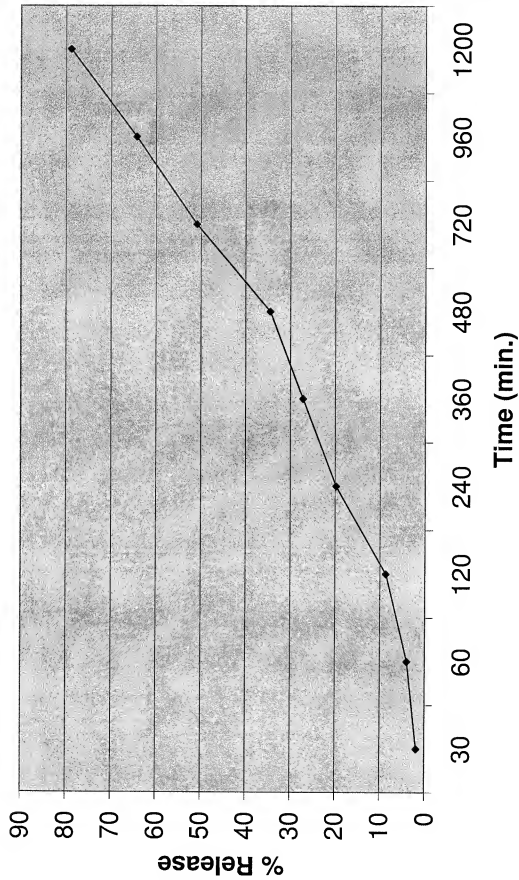




Table II: Non coated Tablet

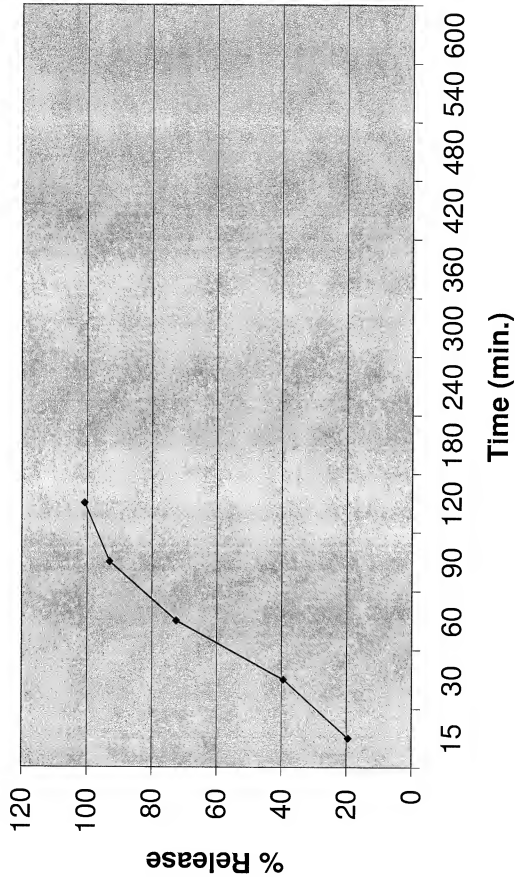


Table II: Hole 19.5 mm2

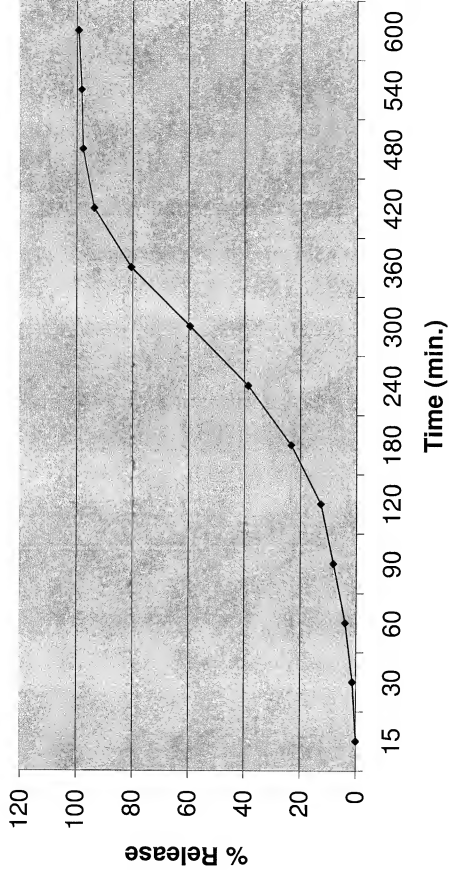


Table II: Hole 38.5 mm2

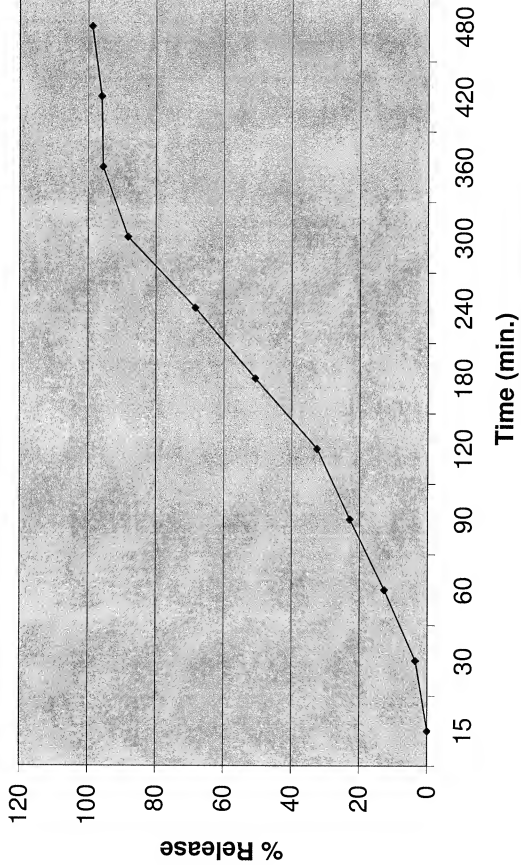


Table III: Non coated tablet

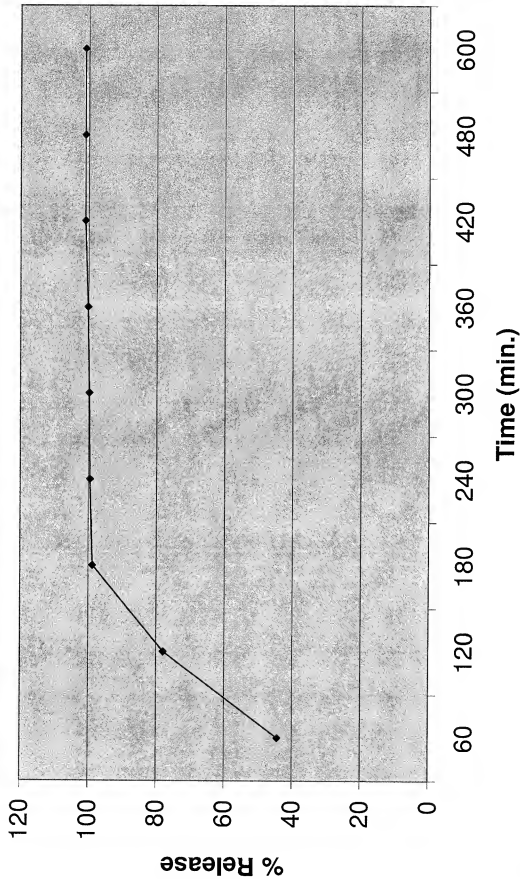


Table III: Hole 19.5 mm2

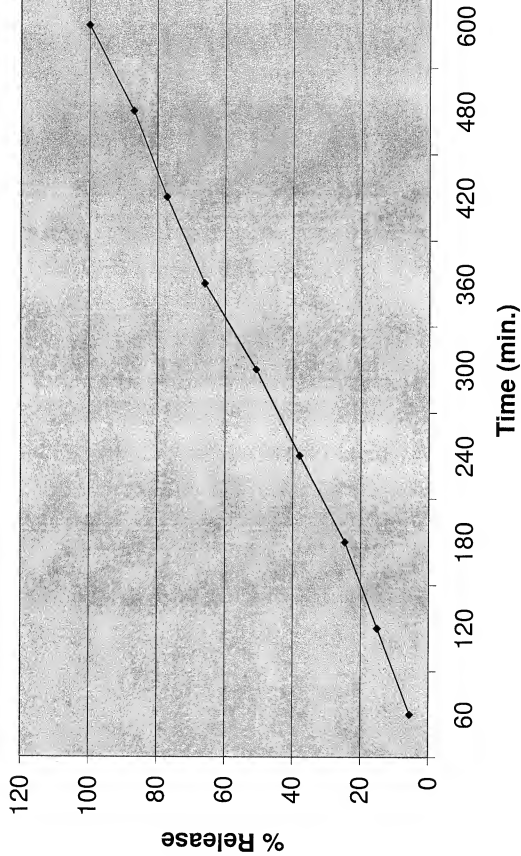


Table III: Hole 38.5 mm2

